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Biotechnology - GE Plants and Animals

2010 Annual Biotechnology Report

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Report Highlights:

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After 12 years of being the second largest producer of biotech crops after the United States, Argentina is now third in the list after Brazil. Due to private industry concerns over the time required for approval of new biotech events, the government is looking for different options to improve efficiency of the process.

Seed companies and farm organizations are in negotiations for an agreement for payment of royalties for biotech events introduced into Argentina, seeking to end a longstanding dispute over payment of royalties.

Section I. Executive Summary:

After 12 years of being the second largest producer of biotech crops after the United States, Argentina is now third after Brazil. Argentina cultivated an area of 21.3 million hectares in the 2009/10 crop season, increasing 1.36 million hectares from the previous year. Almost all soybean area is with biotech seed varieties, while 83 percent of corn area and 97 percent of cotton area are biotech varieties. The area cultivated with the approved corn stacked event represents 31 percent of the total, an important increase of the adoption rate compared to the 2% cultivated during the first crop season after its approval. The first stacked cotton event (MON1445 x MON531) was approved on 2009, and the event showed a high rate of adoption as it represents 78 percent of the total biotech cotton area.

The Government of Argentina (GOA) is seeking ways to reduce the time for approval of new events. Argentine authorities have the goal of shortening the approval process to 24 months, while the average is now 42 months.

Argentina continues to be an important ally of the United States in international issues involving biotechnology and was co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on biotech crop applications. While the lack of a royalty collection system is still an important issue, the Government of Argentina has placed a priority on stimulating biotech research and innovation.

The Argentine Seed Law allows producers to successively use seeds on their own farms. Farmers cannot sell these seeds. This law is interpreted to mean that farmers only have to pay royalties on the original purchase of biotech seeds, but not when they replant seeds that have been selected and saved. According to official numbers, 20 percent of the total area planted with soybeans in Argentina is sown with seeds purchased from authorized dealers; 30 percent with seeds saved by farmers for their own use, and the remaining 50 percent with seeds selected and sold illegally.

The seed industry and representatives of farm organizations are conducting private meetings to reach consensus on a system to pay royalties for new seed technologies. The draft document will define “self use”, establish a mechanism to pay royalties, and create mechanisms to control payments. The goal is that once the document is agreed and signed by the parties, the government would help implement this private agreement.

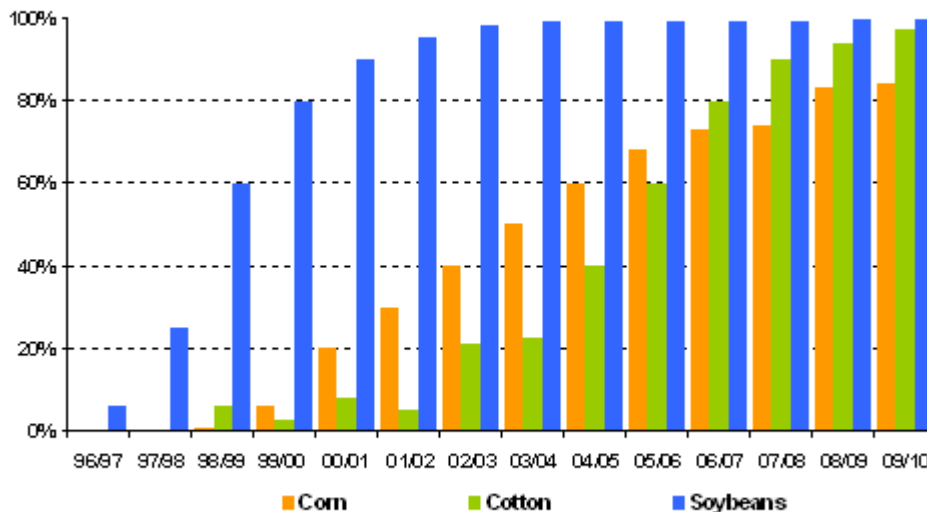
Argentina is active in development of genetically engineered animals for production of pharmaceutical products, but has not approved any genetically modified animals for food consumption (see Section VI Animal Biotechnology).

Section II. Plant Biotechnology Trade and Production:

Argentina is the world's third largest producer of biotech crops after the United States and Brazil, with seventeen biotech crop varieties approved for production and commercialization: one for soybeans (Monsanto 40-3-2), thirteen for corn (Ciba-Geigy 176; AgrEvo T 25; Monsanto 810; NK 603; Novartis Bt 11; Syngenta GA 21; Dow/Pioneer TC 1507; Monsanto NK603 x 810; Pioneer 1507 x NK603, Syngenta Bt11xGA21; Monsanto 89034, Monsanto 88017; and Monsanto 89034x88017), and three for cotton (Monsanto 531; 1445, and 1445 x 531). (Please See Attachment A)

Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 18 million hectares. Argentina also entered in a new stage of biotech development after approving the use and commercialization of stacked events. But as a result of the unsolved royalty issue, multinational seed companies are delaying introduction of new technologies. Monsanto has announced the introduction in 2011 of their RR2 soybeans in Brazil and Paraguay, while in Argentina they have not even requested authorization to sell seed the new variety.

Argentina: Evolution of LMO Area
(Total percentage of each crop)



Source: ArgenBio, 2010

**Argentina: Evolution of LMO cultivated area
(in thousands hectares)**

	TH Soybeans	Bt Com	TH Corn	Bt xTH Corn	Bt Cotton	TH Cotton	Bt x TH Cotton	Total
96/97	370	-	-	-	-	-	-	370
97/98	1.756	-	-	-	-	-	-	1.756
98/99	4.800	13	-	-	5	-	-	4.818
99/00	6.640	192	-	-	12	-	-	6.844
00/01	9.000	580	-	-	25	-	-	9.605
01/02	10.925	840	-	-	10	-	-	11.775
02/03	12.446	1.120	-	-	20	0,6	-	13.586
03/04	13.230	1.600	-	-	58	7	-	14.854
04/05	14.058	2.008	14,5	-	55	105	-	16.241
05/06	15.200	1.625	70	-	22,5	165	-	17.082
06/07	15.840	2.046	217	-	88	232	-	18.423
07/08	16.600	2.509	369	82	162,3	124	-	19.846
08/09	17.000	1.536	320	800	72	210	-	19.938
09/10	18.182	1.408	256	992	42,3	47	367	21.294

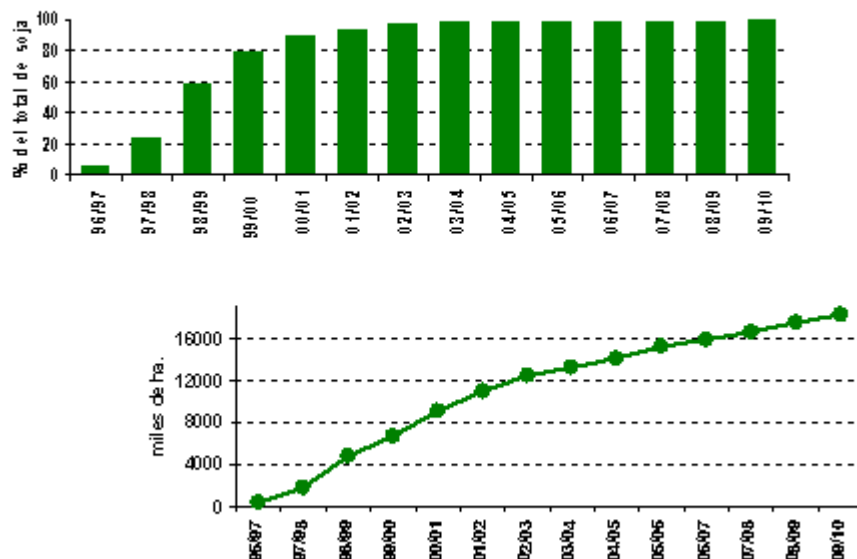
Source: ArgenBio, 2010

Soybeans

Released in 1996, glyphosate tolerant (Roundup Ready) soybeans were the first biotech crop introduced into Argentine agriculture. Since its release, this technology has been adopted at a very high rate, with almost all of the 18 million hectares of soybeans planted for the current season being biotech. The new technology facilitated the incorporation of double crop soybeans (allowing soybeans to be planted following wheat harvest) in many areas where only one crop was planted before the availability of the biotech varieties.

The Argentine soybean economy is geared almost entirely towards exports, with 25 percent exported as soybeans and the rest processed by the oilseed crushing industry (mainly for export). Ninety-three percent of soybean oil and ninety-nine percent of by-products (meals) are exported.

Argentina: Evolution of Herbicide Tolerant Soybeans Area



Source: ArgenBio, 2010

Corn

This will be the third season where Argentine farmers used stacked corn events. In February 2007, the government simplified the approval process for stacked events allowing applications for a transgenic crop combining two already approved events without a full analysis of the new crop. On August 31, 2007 Argentina approved the first stacked gene, Monsanto's NK603x810.

The first triple stacked event was approved on May 28, 2008. It is Pioneer's corn trait product containing the insect protection trait (*Herculex I technology*), resistance to the Amonium Glufosinate (*Liberty Link technology*) and to Glyphosate (*Round Up Ready Technology*).

On December 21, 2009, Syngenta received approval for its stacked corn trait Bt 11x GA 21, which combines Glyphosate tolerance and resistance to lepidoptera insects technology.

Biotech corn adoption represents 83 percent of total corn planted area. In the 2009/2010 crop season the area planted with stacked events (Bt x TH) accounted for 31 percent of the total area (approx 992,000 hectares). The rest of the biotech corn planted corresponded to Bt, estimated in 1.40 million hectares, representing approx 44 percent, and glyphosate tolerant variety (GA 21) with 256,000 hectares planted, corresponding to 8 percent of the total biotech corn.

During 2010 Monsanto received approval for three new varieties : Mon89034 (resistance to Lepidoptera insects); Mon88017 (combined resistance to Lepidoptera and glyphosate tolerance), and Mon89034x88017 (combined resistance to Lepidoptera, coleoptera and tolerance to glyphosate).

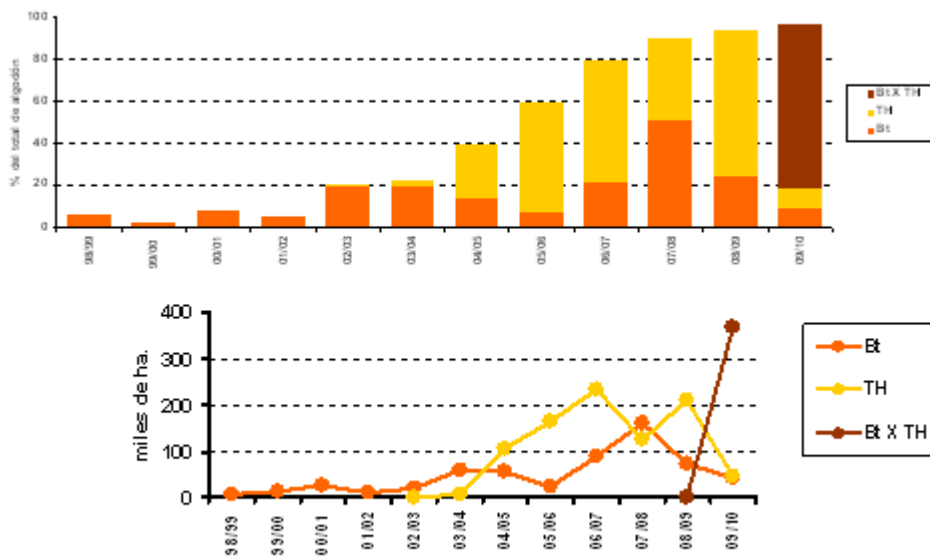
Cotton

Biotech cotton adoption represents 97 percent of total cotton planted area. In the 2009/10 crop season, 78 percent (367,000 hectares) was planted with the stacked event (Bt x TH), 10 percent (47,000 hectares) was planted with the glyphosate resistant event (TH), and the remaining 9 percent (42,000 hectares) was planted with the Bt event.

In December 2009, Argentina approved the first cotton stacked gene, Monsanto's MON 1445 x Mon 531 (glyphosate tolerance and resistance to Lepidoptera). The graphics below show the high rate of adoption of this event by the Argentine farmers.

The National Institute of Agricultural Technology (INTA) is conducting research of colored cotton varieties. The release in the market is expected in a few more years and will be focused on niche markets for small and medium producers.

Argentina: Evolution of area planted with Bt, TH y Bt X TH cotton



Source: ArgenBio, 2010

Oilseed - Rape

The National Seed Institute (INASE) has forbidden the import of biotech rapeseed (through Resolution 305/07 of 2007) and established a requirement for a certificate stating the absence of biotech seeds in rapeseed shipments.

Section III. Plant Biotechnology Policy: Biosafety Regulatory System

The evaluation of new events takes place on a case-by-case basis, taking into consideration the process only in those cases where the environment, the agricultural production or the health of humans or animals could be at risk.

The key office within the Ministry of Agriculture that centralizes all biotech activities and information is the Biotechnology Direction, created in 2009. This office coordinates three technical areas: biosafety issues (the head is a member of the National Advisory Committee on Agricultural Biotechnology, CONABIA), policy analysis and formulation and regulatory design.

The approval process takes approximately 42 months, which is generally considered very long considering the current dynamics of the biotech industry and the fact that Brazil is approving trials at a faster rate than Argentina, with 18 biotech events approved in just two years. The main problem the GOA faces is the lack of both human and financial resources. Understaffing and outdated regulations hold back field trials and commercial release. According to contacts within CONABIA, the flow of applications has tripled from 1999 to 2009. GOA officials have publically stated their goal to shorten the approval process to 24 months, although they have not specified how this will be accomplished.

The approval process for commercialization of biotech seeds involves different agencies within the Ministry of Agriculture:

-National Advisory Committee on Agricultural Biotechnology (CONABIA)

Role: Evaluate impact in the agricultural ecosystem. It ensures compliance with Resolution 39. (Please See Appendix B) and also with Resolution 60, that regulates stacked genes.

CONABIA is a multidisciplinary and inter-institutional organization with advisory duties. Its main responsibility is to assess, from a technical and scientific perspective, the potential environmental impact of the introduction of biotech crops in Argentine agriculture. CONABIA reviews and advises the Secretariat on issues related to trials and/or the release into the environment of biotech crops and other products that may be derived from or contain biotech crops. It is a multi-sectorial organization made up by representatives from the public sector, academia and private sector organizations related to agricultural biotechnology. CONABIA members perform their duties as individuals and not as representatives of the sector they represent, and they are active participants in the international debate on biosafety and the related regulatory processes.

CONABIA has reviewed over 1000 permit applications since its creation, developing new capacities as the sector required. CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Secretary of Agriculture. In absence of a law governing its reviews, there are limits in its ability to penalize those who do not comply with stipulated procedures.

-National Service of Agricultural and Food Health and Quality (SENASA)

Role: Evaluate the biosafety of food products derived from biotech crops for human and animal consumption.

-National Direction of Agricultural Food Markets (DNMA)

Role: Evaluate commercial impact on export markets by preparing a technical report in order to avoid a

negative impact on Argentine exports. DNMA mainly analyzes the status of the event under study in the destination markets. They focus on whether the product has been approved or not and, as a result, whether the addition of this event to Argentina's export supply might represent a potential barrier to the access to these markets.

-National Seed Institute (INASE)

Role: Establish requirements for registration in the National Registry of Cultivars.

Upon completion of all of the steps mentioned above, CONABIA's Office of Technical Coordination compiles all pertinent information and prepares a final report to the Secretary of Agriculture, Livestock, Fisheries and Food for final decision. (Attachments C & D)

Traceability

There is no official system in place. At this stage, only private companies (authorized labs) have the capability to perform the required tests. For example, the National Institute of Agricultural Technology (INTA) does analysis on a private basis.

Labeling

There is no specific regulation in Argentina in reference to labeling biotech products. The current regulatory system is based on the characteristics and identified risks of the product and not in the production process of that product. There is no regulation governing the use of labels such as "BIOTECH FREE" or "NON-GMO".

The policy of the Ministry of Agriculture on labelling in international fora is that it should be based on the type of food product derived from a specific biotech seed taking into account that:

- Any food product obtained through biotechnology and substantially equivalent to a conventional food product, should not be subject to any specific mandatory label.
- Any food product obtained through biotechnology and substantially different from a conventional food product for any specific characteristic may be labelled according to its characteristics as food product, not according to aspects concerning the environment or production process.
- Differential labelling is not justified, as there is no evidence that demonstrates that food products produced through biotechnology may represent any risk for the consumers' health.
- In the case of agricultural products, as the majority of them are commodities; the identification process would be complicated and expensive. The increased production costs as a result of labelling would end up being paid by the consumers, without assuring that this would represent better information or increased food security.

Stacked events

In 2007, under Resolution 60 which complements resolution 39, Argentina approved a different treatment for stacked genes. Approval is based in a case by case evaluation under which the applicant needs to submit a letter simultaneously to SAGPyA (Office of Biotechnology) and to SENASA

requesting authorization for commercialization of the specific stacked event.

The evaluation is based on possible effects when the individual events affect related metabolic patterns. Also, in order to evaluate the possible effects of the stacked event in the ecosystem, as well as the food biosafety evaluation, CONABIA and/or SENASA will determine whether they request additional information from the applicant.

Coexistence

The Argentine Seed Association (ASA), created in 1999 the Insect Resistance Management Program in Bt. The objective of the program is to promote a responsible use of technology in order to delay any potential resistance development and immediately detect any change in the susceptibility of insect populations by putting in place a refuge system. To carry out this goal, the program is based on three pillars:

Research: Scientists from INTA (National Institute of Agricultural Technology) conduct permanent studies to improve the understanding of pest biology and to monitor the sensitivity to the Bt protein. The goal is to continuously improve tools used to evaluate recommendations regarding resistance management provided to farmers and used to detect any possible change in the susceptibility of the insect population.

Communication: Farmers, as users of the technology, have a key role in its preservation; therefore their knowledge is fundamental to achieve a responsible and successful management of Bt corn varieties.

Evaluation of a proper use of technology: The periodic evaluation of farmers adoption of refuges allows an assessment of the success of the program and to improve the tools to adjust communication.

CONABIA approved this system and periodically receives reports submitted by the Argentine Seed Association (ASA).

Intellectual Property Rights – Royalties

Argentina is a major producer and exporter of agricultural biotechnology products, yet it does not have an adequate and effective system in place to protect the intellectual property rights of new plant varieties or plant-related technology. Penalties for unauthorized use of protected seed varieties are negligible. Judicial enforcement procedures in Argentina likewise are ineffective as a mechanism to prevent the unauthorized commercial use of protected varieties.

Argentine Intellectual Property (IP) laws are based on UPOV-78, which provides strong protection for the right of farmers to save and replant seeds, and exempts them from providing explanations on how selected seeds were used. The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotech inventions, renders Argentina's intellectual property system inadequate from the perspective of the biotechnology industry.

Monsanto, grower organizations, and commodity exporters have not reached agreement on a solution to the continued high level of saved and illegally traded RR soybeans. In January 2004, Monsanto announced that it would cease investments in and sales of RR soybeans in Argentina. The central issue,

according to Monsanto, was its inability to fully collect RR-technology-related royalties from Argentine growers. Monsanto applied for and was denied a patent on RR soybeans, a decision it appealed unsuccessfully with the Argentine Supreme Court. Argentine law currently allows farmers to save seed from one harvest and to use it the following year if a royalty is paid to the original seed breeder. However, it is illegal to sell, trade, or pass saved seed from one producer to another.

In May 2004, Argentina's National Seed Institute implemented Resolution 44/2004, requiring that each sack of seed be labeled with quantity, unit price, total sales price, and seed species, type or variety.

Due to continued illegal seed sales, Monsanto initiated legal actions in European Countries in 2005 against unlicensed shipments of soybeans, soybean meal, and other soy products containing the RR gene, but was not successful in the legal action.

The main private sector stakeholders (as members of the Biotechnological Value Creation Committee of the Argentine Seed Trade Association) are conducting private meetings to reach consensus on an agreement to safeguard the incorporation of new patentable technologies in seeds. This includes the definition and limits on "self use", and mechanisms to collect and control payment of royalties. The goal is that once the document is signed, the parties would request that the government help implement the agreement.

Biosafety Law

Argentina does not have a biosafety law in place. Initial discussions on developing a biosafety law took place in 2001, but due to the institutional and economic crisis that broke out in December 2001, the draft was never discussed in Congress and there is no evidence that it will be in the near future. Private sources have indicated that due to the current conditions at Congress, a Biosafety Law is considered a long term objective.

International Negotiation Fora

Cartagena Biosafety Protocol

In the international biotechnology negotiation arena, the Cartagena Biosafety Protocol (CBP) is probably the most significant issue. Argentina signed the Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet signed its ratification. Argentina is currently undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take in this respect.

Codex Alimentarius and Other Agreements

During 2009 Argentina chaired the Codex working group on methods of analysis for GM foods. In addition, the country is actively working to reach consensus on biotech labelling and actively participating to avoid potential trade disruptions and unnecessary cost increases.

Ongoing Issues at National Level

The GOA 15 year Strategic Plan

The plan proposes to diversify the application of biotechnology, both in the number of tools and in productive activities. It advocates creating an appropriate environment (in political, legal and public acceptance issues) for the creation and development of biotechnology-based companies, and also to improve the consolidation of the existing ones. It proposes to assist increasing agricultural production, while preserving and improving the quality of life of the present and future generations. One of the strengths of the plan resides on its flexibility: the accomplishment of the plan has been based on the implementation of a scheme that is built almost simultaneously along its execution, including the revision of objectives, goals and main actions.

Draft Biotech Promotion Law

This law (N. 26.270) was created to promote biotech initiatives, to stimulate, through fiscal benefits, research, development and investment in products, services or biotech processes. However, the law has not been implemented yet.

Section IV. Plant Biotechnology Marketing Issues: Public Perception – Consumer's Attitude

Most Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotechnology to improve yields and nutritional value of crops while decreasing the input of chemical pesticides. Argentine consumers do not see biotech products as a benefit to themselves but they can see these products as economically productive to farmers and multinationals but still are hesitant about supporting the technology. As Argentina has been a leader in the adoption of biotechnology, there is a need for dialogue and communication among scientists, farmers, private companies, consumers, government, and regulatory organizations.

Under the *UNEP-GEF* project (United Nations Environment Program – Global Environment Facility), SAGPyA performed and released a survey among producers and consumers that provided the following results:

Producers: (survey conducted at the two most important local farming shows)

90% of the consulted producers reported that, (although some showed confusion and hesitation), they knew, worked with or at least heard about biotech,

75% stated that consumption of biotech foods DO NOT present any risks to the human health,

12% expressed that they know the Argentine regulatory system, and half of them considered that it is safe,

57% stated that if the GOA were to decide to segregate, they would still use biotech seeds,

82% stated that biotechnology is a tool that solves problems that no other technology has been able to solve, and

49% stated that biotechnology does not present a serious ethical problem.

Consumers (survey conducted in various supermarkets):

80% are informed mainly thru TV, 55% thru radio and 50% thru newspapers,

13% DO NOT read the label of a product before purchasing it,

60% have confidence in what they consume,

64% consumers stated that, albeit reporting some confusion and hesitation, they heard about biotech foods,

43% agreed with the use of biotechnology in agriculture

40% stated that consumption of biotech products poses some risks to human health

94% of all consulted (both producers and consumers) stated that the government should provide more information regarding the benefits and risks of biotech products.

Public Participation, Education and Awareness Activities

In 2004 the GOA included biotechnology as a mandatory subject in schools, but most teachers did not have any training or access to sources for information. At that time a panel of experts from Argenbio (the national non profit biotechnology association) designed a training course and educational materials that are now offered free of charge to schools around the country. As of today, more than 10,000 teachers have received the “Por que Biotecnologia” (Why Biotechnology) training.

Section V. Plant Biotechnology Capacity Building and Outreach: 2005

- A. The Agricultural Counselor accompanied U.S. State Department Biotech Negotiator to participate in a series of biotechnology discussions organized by FAS Buenos Aires.
- A. FAS Buenos Aires in concert with FAS Santiago organized and accompanied a Southern Cone CODEL to the United States to demonstrate how the United States uses and regulates agricultural biotechnology.
- A. FAS Buenos Aires organized a biotechnology workshop in several Argentine provinces, targeting universities and media. Dr. Wayne Parrott, from Georgia University was the invited speaker.
- A. FAS Buenos Aires participated in the organization of the NABI/CAS meeting in Buenos Aires.
- A. FAS Buenos Aires participated in the meeting of the parties prior to CBP in Canada.
- A. FAS Buenos Aires selected one Argentine journalist to participate in a US Grains Council activity in the United States.

2006

A. FAS Buenos Aires organized and accompanied a group of Argentine journalists to the United States to demonstrate how the United States uses and regulates agricultural biotechnology.

2007

A. FAS Buenos Aires organized and accompanied a group of Argentine journalists to the United States to demonstrate how the United States uses and regulates agricultural biotechnology.

2008

- A. FAS Buenos Aires selected and facilitated the trip of an Argentine expert who was key speaker of a biotech Conference held in South Africa, Mozambique and Madagascar.

2009

- A. AgCounselor participated as speaker of the Biotech Forum in Rosario, Santa Fe Province.
- B. FAS Buenos Aires sponsored a trip for Argentine biotech expert to participate in a hemispheric seminar organized by the US Codex Office in Lima, Peru.

2010

- A. FAS Buenos Aires coordinated a trip for five Argentine biotech experts to participate in a hemispheric meeting organized by the US Codex Office in Panama City, Panama.

Proposed Activities

FAS Buenos Aires proposes a continuation of education and outreach as well as a more targeted information campaign. Specific activities may include:

- Workshops in different cities to target audiences around the country,
- A two-day conference directed mainly to Congressmen, but also to media, academia and government officials among others,
- Activities with local universities to demonstrate the benefits of Biotechnology in Argentina
- Continue Cooperator, Cochran, and International Visitor program activities,
- Special activities designed for consumer association leaders and consumers in general,
- Workshops especially directed to medical doctors and nutritionists, explaining the innocuousness of biotech products;
- Workshop in risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.
- Technical workshop to discuss treatment and analysis of stacked biotech events.
- Work with Senators and Representatives on the regional forum created after the Southern Cone Reverse CODEL; and,
- Meetings to develop lines of communication between the GOA and the USG during the review process of biotech events.

Section VI. Animal Biotechnology:

I. Development and Use

Argentina was the first country in Latin America to develop two generations of genetically modified cows capable of producing Human Growth Hormone. In March 2006, CONABIA and SENASA (National Service of Agricultural and Food Health and Quality) approved the first step in the process to authorize the production of the human growth hormone from milk. The next step that needs to be completed is approval by the Secretary of Public Health.

The cloned (but also transgenic) calves, Pampa Mansa II, Pampa Mansa III and Pampero, developed by the Biosidus Company, carry a gene that produces human growth hormone in milk. The milk produced by just one cow can meet the demand of the entire country. It is estimated that 1,000 Argentine children currently require such hormone therapy.

In 2007, Biosidus Company developed another line of cloned calves, this time to produce insulin. After several years of research and 4 million dollars investment, “Patagonia” was the first calf born. In this case, the insulin produced by 25 cows like Patagonia will meet the annual demand of the entire country at a lower cost (30% less than the currently used insulin). The intention is to produce enough insulin to be able to export in the near future.

And finally in late 2008 with the “Porteña” dynasty, Bio Sidus has accomplished the production of a hormone for bovine growth from cloned and transgenic calves, which will increase the production of cow milk up to 20%. The country will thus be the top world producer and exporter of this product. For this project the gene of the hormone for bovine growth was added to the bovine cells, so that this may be produced inside the udder and secreted to the milk of these animals.

This Porteña dynasty is not focused on the pharmaceutical market but the rural sector, where the hormone for bovine growth is used to increase the production of milk. Thus, this new product has a totally exporting profile, since it is mainly used in the USA, Mexico and Brazil, among other countries.

II. Regulation

The regulatory system applied to transgenic animals is the same used to evaluate plant events, that is, the evaluation takes place on a case by case basis. The agencies involved are CONABIA, SENASA, and the National Direction of Agricultural Food Markets. In the event of evaluations for pharmaceutical use, there is another agency involved, the National Administration of Medicines, Food and Medical Technology (ANMAT in Spanish).

The norm applied is Number 57 from 2003. Original text may be found at:

<http://www.minagri.gob.ar/SAGPyA/areas/biotecnologia/90=ENGLISH/01-Regulations/index.php>

III. Stakeholder/Public Opinion

There haven't been reactions in favor or against the development of transgenic animals. The main reason may be that the first cows produced were intended for pharmaceutical use, and that in general produces less reaction.

IV. Outreach, Needs and Strategies

No activities have been developed specifically on genetic engineered animals.

